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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,274	10/21/2003	Ramon Eritja	030577	8626

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EXAMINER	
WOOLWINE, SAMUEL C	
ART UNIT	**PAPER NUMBER**
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,274	ERITJA ET AL.	
	Examiner	Art Unit	
	Samuel Woolwine	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-11, in the reply filed on 12/19/2006 is acknowledged.

Claims 12 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/19/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Soliva et al (Nucleic Acids Research, vol 28, no 22, pp4531-4539, published Nov 15, 2000).

With regard to claim 1, Soliva teaches an antiparallel oligonucleotide triplex comprising the substitution of at least one purine in said triplex with at least one 8-aminopurine (8-aminoguanine, represented by **1**, see page 4533, "Oligonucleotide synthesis"). See for example Table 3, where Soliva describes an experiment to

determine the thermodynamic parameters for transition of a triple helix (formed from a hairpin oligonucleotide h_{26} and another oligonucleotide s_{11}) to its dissociated form. Note that there is no explicit definition of "antiparallel oligonucleotide triplex" in the instant specification. Therefore there is nothing in the claim to structurally distinguish the oligonucleotide triplex taught by Soliva from the claimed triplex.

With regard to claim 2, Soliva teaches an oligonucleotide hairpin (see for example Table 3, oligonucleotide h_{26}) comprising a first oligonucleotide strand (GAAG**1**A**1**GA**1**A), a linker (TTTT), and a second oligonucleotide strand (TCTCCTCCTTC), wherein said first oligonucleotide strand is substantially a purine strand comprising at least one 8-aminopurine (8-aminoguanine, represented by **1**, see page 4533, "Oligonucleotide synthesis"), and wherein said linker is connected to either the 3' end of said first oligonucleotide strand and the 5' end of said second oligonucleotide strand or to the 5' end of said first oligonucleotide strand and the 3' end of said second oligonucleotide strand. See Table 3.

With regard to claim 3, Soliva teaches 8-aminoguanine. See Table 3.

With regard to claim 4, Soliva teaches a tetrathymidine linker. See Table 3.

With regard to claims 5 and 6, note that the hairpin oligonucleotide h_{26} taught by Soliva can also be considered to comprise a first oligonucleotide strand (GAAG**1**), a linker (A**1**), and a second oligonucleotide strand (GA**1**ATTTTTCTCCTCCTTC), wherein said first oligonucleotide strand is substantially a purine strand comprising at least one 8-aminopurine (8-aminoguanine, represented by **1**, see page 4533, "Oligonucleotide synthesis"), and wherein said linker is connected to either the 3' end of said first

oligonucleotide strand and the 5' end of said second oligonucleotide strand or to the 5' end of said first oligonucleotide strand and the 3' end of said second oligonucleotide strand. Furthermore the second oligonucleotide strand comprises guanine and adenine (claim 5) as well as guanine and thymine (claim 6).

With regard to claim 7, no specific target oligonucleotide is recited in the claim. Any nucleotide sequence, including the first strand of the oligonucleotide h_{26} taught by Soliva in figure 3, is inherently complementary to a target oligonucleotide. And in fact Soliva teaches a target oligonucleotide, designated s_{11} in Table 3.

With regard to claim 8, Soliva teaches an oligonucleotide duplex comprising a first oligonucleotide strand and a second oligonucleotide strand, wherein said first oligonucleotide strand is substantially a purine strand comprising at least one 8-aminopurine, and wherein said second oligonucleotide strand is substantially complementary to and chemically bound to said first oligonucleotide strand. See Table 3, oligonucleotide h_{26}.

With regard to claim 9, Soliva teaches a method for stabilizing an antiparallel oligonucleotide triplex, comprising the steps of providing an antiparallel oligonucleotide triplex comprising a first, second, and third oligonucleotide strand, wherein at least one oligonucleotide strand comprises a purine, and replacing said purine with an 8-aminopurine. See Table 2, where Soliva teaches a first and second strand (which are the first and second strands of hairpin oligonucleotide h_{26} discussed above) and a third oligonucleotide strand, s_{11}. Note that Soliva demonstrates higher melting temperature

of the oligonucleotide triplex (therefore increasing stability thereof) by replacing guanine with 8-aminoguanine (represented by **1**, see page 4533, "Oligonucleotide synthesis").

With regard to claim 10, Soliva teaches an antiparallel triplex comprising a first oligonucleotide strand comprising at least one 8-aminopurine, a linker connected to said first strand, a second oligonucleotide strand connected to the opposite end of said linker from the first oligonucleotide strand and capable of forming a hairpin with said first oligonucleotide strand, and a third oligonucleotide strand comprising pyrimidines, wherein said third oligonucleotide strand is substantially complementary to and antiparallel to said first oligonucleotide strand. See Tables 2 and 3.

With regard to claim 11, the specification does not contain an explicit definition as to what constitutes a "Hoogsteen configuration" or a "reverse Hoogsteen configuration" and therefore does not structurally distinguish over the triplexes taught by Soliva.

Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Eritja et al (US 2006/0008813, published Jan 12, 2006, priority date Jan 22, 2002), which is the publication for US application 10/966,672.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With regard to claim 1, Eritja teaches in paragraph [0052] that an embodiment of his invention involves the formation of an antiparallel triple helix comprising one or more 8-aminopurines.

With regard to claims 2 and 3, Eritja teaches an oligonucleotide comprising a polypyrimidine sequence, a polypurine sequence comprising at least one of 8-aminoadenine, 8-aminoguanine or 8-aminohypoxanthine, and a linker connecting the two sequences (see claims 9 and 12). A "polypurine sequence" is a species of an oligonucleotide strand that anticipates the "substantially a purine strand" as found in instant claim 2, while 8-aminoadenine, 8-aminoguanine and 8-aminohypoxanthine are anticipate the 8-aminopurines found in instant claims 2 and 3. A polypyrimidine sequence is a species that anticipates the "second oligonucleotide strand" as found in instant claim 2. Furthermore, the linker orientations taught by Eritja in claims 10, 11, 13 and 14 of the '672 application anticipate the limitation regarding linker orientation of instant claim 2.

With regard to claim 4, Eritja teaches a tetrathymine linker (see paragraph [0083]).

With regard to claim 5, Eritja teaches an oligonucleotide meeting the limitations of claim 2, wherein the second oligonucleotide strand comprises guanine and adenine (see page 4, Table 1, "B-22AMMA", for example).

With regard to claim 6, Eritja teaches an oligonucleotide meeting the limitations of claim 2, wherein the second oligonucleotide strand comprises guanine and thymine (see page 4, Table 1, "B-22AMMA", for example).

With regard to claim 7, any oligonucleotide, including those taught in the claims of the '672 application, are inherently complementary to a target oligonucleotide (i.e. every oligonucleotide sequence has a corresponding complementary sequence which can be considered a "target").

With regard to claim 8, the only distinction from instant claim 2 is the added requirement that the second oligonucleotide is substantially complementary to the first oligonucleotide. Eritja teaches an oligonucleotide meeting the limitations of claim 2, wherein the second oligonucleotide strand is substantially complementary to the first (see page 4, Table 1, "B-22AMMA", for example).

With regard to claims 9-11, Eritja teaches replacing adenine with 8-aminoadenine to increase the stability of the triple helix comprising Hoogsteen bonds (see paragraphs [0006]-[0007]). There is no explicit definition of "antiparallel oligonucleotide triplex", "Hoogsteen configuration" or "reverse Hoogsteen configuration" which structurally distinguishes over the triple helix taught by Eritja.

Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Eritja et al (US 2004/0029160, published Feb 12, 2004, priority date May 24, 2002), which is the publication for US application 10/446,201.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With regard to claim 1, Eritja teaches an antiparallel oligonucleotide triplex comprising at least on 8-aminopurine (see claim 1 of the '201 application).

With regard to claim 2, Eritja teaches a parallel hairpin comprising a purine part, a pyrimidine part, and a linker, wherein the purine part comprises at least one 8-aminopurine (see claim 1 of the '201 application). Eritja teaches the linker connects the 5' end of the purine part to the 5' end of the pyrimidine part (see claim 10 of the '201 application).

With regard to claim 3, Eritja teaches the at least one 8-aminopurine is 8-aminoadenine, 8-aminoguanine or 8-aminohypoxanthine (see claims 6-8 of the '201 application).

With regard to claim 4, Eritja teaches a tetrathymine linker (see claim 5 of the '201 application).

With regard to claim 5, see table at middle of page 10, RE-2AG (G^N is 8-aminoguanine; see for example paragraph [0035]), wherein the second oligonucleotide comprises guanine and adenine.

With regard to claim 6, see figure 15, B-22AMMGA, (A^N is 8-aminoadenine; see for example paragraph [0035]), wherein the second oligonucleotide comprises guanine and thymine.

With regard to claim 7, any oligonucleotide, including those taught by Eritja, are inherently complementary to a target oligonucleotide (i.e. every oligonucleotide

sequence has a corresponding complementary sequence which can be considered a "target").

With regard to claim 8, the only distinction from instant claim 2 is the added requirement that the second oligonucleotide is substantially complementary to the first oligonucleotide. This limitation is taught by Eritja in claim 1 of the '201 application, which teaches a hairpin comprising a polypurine sequence and a polypyrimidine sequence, wherein "said polypurine sequence is complementary to and parallel to said first polypyrimidine sequence".

With regard to claim 9, Eritja teaches a method for stabilizing an antiparallel oligonucleotide triplex by replacing natural purines in the triplex with 8-aminopurines (see paragraph [0057]).

With regard to instant claims 10 and 11, Eritja teaches an antiparallel oligonucleotide triplex as discussed above (see claim 1 of the '201 application). Furthermore, Eritja teaches such a triplex wherein the target sequence of the triplex is arranged in Hoogsteen orientation with respect to the hairpin (see claim 16 of the '201 application).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 3, 7 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-14 of copending Application No. 10/966,672. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

With regard to instant claims 2 and 3, claims 9 and 12 of the '672 application teaches an oligonucleotide comprising a polypyrimidine sequence, a polypurine sequence comprising at least one of 8-aminoadenine, 8-aminoguanine or 8-aminohypoxanthine, and a linker connecting the two sequences. A "polypurine sequence" is a species of an oligonucleotide strand that is "substantially a purine strand" as found in instant claim 2, while 8-aminoadenine, 8-aminoguanine and 8-aminohypoxanthine are species of 8-aminopurines as found in instant claim 2, and are identical to the species found in instant claim 3. A polypyrimidine sequence is a species of a "second oligonucleotide strand" as found in instant claim 2. The specific limitations of claim 9 of the '672 application render the more generic limitations of instant claim 2 obvious. Furthermore, the linker orientations taught in claims 10, 11, 13 and 14 of the '672 application cover the limitation regarding linker orientation of instant claim 2.

With regard to instant claim 7, any oligonucleotide, including those taught in the claims of the '672 application, are inherently complementary to a target oligonucleotide (i.e. every oligonucleotide sequence has a corresponding complementary sequence which can be considered a "target").

With regard to instant claim 8, the only distinction from instant claim 2 is the added requirement that the second oligonucleotide is substantially complementary to the first oligonucleotide. This limitation is taught in claim 12 of the '672 application because in that claim, the polypurine sequence forms a parallel double-stranded structure with the polypyrimidine sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 3, 7 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/917,778. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

With regard to instant claims 2 and 3, claim 5 of the '778 application teaches a method using a parallel-stranded hairpin comprising a purine part (a species of the instant "substantially" purine strand), a pyrimidine part (a species of the instant second oligonucleotide strand) and a linker connecting the two parts according to instant claim 2, wherein the purine part comprises one of 8-aminoadenine, 8-aminoguanine and 8-aminohypoxanthine (as found in instant claim 3). In teaching a use for a structurally-

defined species of the instant oligonucleotide, claim 5 of the '778 application renders the generic structure of the instant oligonucleotide obvious.

With regard to instant claim 7, any oligonucleotide, including those taught in the claims of the '778 application, are inherently complementary to a target oligonucleotide (i.e. every oligonucleotide sequence has a corresponding complementary sequence which can be considered a "target").

With regard to instant claim 8, the only distinction from instant claim 2 is the added requirement that the second oligonucleotide is substantially complementary to the first oligonucleotide. This limitation is taught in claim 5 of the '778 application, which is directed to a method using a "parallel-stranded hairpin".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 3, 7 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 10/912,032. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

With regard to instant claims 2 and 3, claims 1-6 of the '032 application teaches a parallel-stranded hairpin comprising a purine part (a species of the instant "substantially" purine strand), a pyrimidine part (a species of the instant second oligonucleotide strand) and a linker connecting the two parts according to instant claim 2, wherein the purine part comprises one of 8-aminoadenine, 8-aminoguanine and 8-

aminohypoxanthine (as found in instant claim 3). In teaching a structurally-defined species of the instant oligonucleotide, claims 1-6 of the '778 application render the generic structure of the instant oligonucleotide obvious.

With regard to instant claim 7, any oligonucleotide, including those taught in the claims of the '032 application, are inherently complementary to a target oligonucleotide (i.e. every oligonucleotide sequence has a corresponding complementary sequence which can be considered a "target").

With regard to instant claim 8, the only distinction from instant claim 2 is the added requirement that the second oligonucleotide is substantially complementary to the first oligonucleotide. This limitation is taught in claims 1-6 of the '032 application, which are directed to a "parallel-stranded hairpin".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7, 8, 10 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-8, 10 and 16 of copending Application No. 10/446,201. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

With regard to instant claim 1, claim 1 of the '201 application teaches an antiparallel oligonucleotide triplex comprising at least one 8-aminopurine. The only

difference between the two claims is that claim 1 of the '201 represents a species of the more generic triplex of instant claim 1.

With regard to instant claims 2 and 3, claim 1 of the '201 application teaches a parallel hairpin comprising a purine part (a species of the instant "substantially" purine strand), a pyrimidine part (a species of the instant second oligonucleotide strand) and a linker, wherein the purine part comprises at least one 8-aminopurine. Claims 6-8 of the '201 application teach the at least one 8-aminopurine is 8-aminoadenine, 8-aminoguanine or 8-aminohypoxanthine (as found in instant claim 3). Claim 10 of the '201 application teaches a method of making such a hairpin wherein the linker connects the 5' end of the purine part to the 5' end of the pyrimidine part. In teaching a structurally-defined species of the instant oligonucleotide, claims 1, 6-8 and 10 of the '201 application render the generic structure of the instant oligonucleotide obvious.

With regard to instant claim 4, claim 5 of the '201 application teaches a tetrathymine linker.

With regard to instant claim 7, any oligonucleotide, including those taught in the claims of the '201 application, are inherently complementary to a target oligonucleotide (i.e. every oligonucleotide sequence has a corresponding complementary sequence which can be considered a "target").

With regard to instant claim 8, the only distinction from instant claim 2 is the added requirement that the second oligonucleotide is substantially complementary to the first oligonucleotide. This limitation is taught in claim 1 of the '201 application, which teaches a hairpin comprising a polypurine sequence and a polypyrimidine sequence,

wherein "said polypurine sequence is complementary to and parallel to said first polypyrimidine sequence".

With regard to instant claims 10 and 11, claim 1 of the '201 application teaches an antiparallel oligonucleotide triplex as discussed above. Furthermore, claim 16 of the '201 application teaches such a triplex wherein the target sequence of the triplex is arranged in Hoogsteen orientation with respect to the hairpin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SCW

3-19-07

YOUNG J. KIM
PRIMARY EXAMINER